510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K112435

AUG - 5 2011

Submitter

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Date Prepared:

August 1, 2011

Device name and classification:

- **Device Name:** ECG-6 Series Electrocardiograph
- **Classification Name:** 870.2340 Electrocardiograph
  Product code: DPS
- **Regulatory Class:** Class II

Predicate Device:

SE-601 Series Electrocardiograph K090367 Manufacturer: EDAN Instruments

Device Description:

ECG-6 series Smart ECG includes three models ECG-6 Pro, ECG-6 Plus and ECG-6.

Device features include as follows:

- Portable, lightweight design
- Easy data input and operation
- Alphanumeric keyboard and one-touch operation
- Built-in rechargeable battery, AC/DC power supply
- Automatic analysis and diagnostic software (SEMIP) for adults
- Heart rate variability (HRV) analysis
- Internal thermal printer and external printer
- Support external archiving: USB flash disk, card reader
- Data transmission to PC via Ethernet or serial port

Intended Use:

The intended use of the ECG-6 Series Electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface with ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is only intended to be used on adult patients and is offered to clinicians on an advisory basis only.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

The following safety standards are conducted on the subject device:

- Software testing
- Risk analysis
- Safety testing
- Performance test

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the ECG-6 Series Electrocardiograph. This premarket notification submission demonstrates that ECG-6 Series Electrocardiograph is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG - 5 2011

Advanced Instrumentations, Inc.
c/o Dr. Jorge Millan
Official Correspondent for Advanced Instrumentations
Hialeah Technology Center
601 West 20 St
Hialeah, FL 33010

Re: K112135
Trade/Device Name: ECG-6 Series Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 19, 2011
Received: July 26, 2011

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112135

Device Name:

ECG-6 Series Electrocardiograph

Indications for Use:

The intended use of the ECG-6 Series Electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface with ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is only intended to be used on adult patients and is offered to clinicians on an advisory basis only.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112135